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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,211	12/04/2001	Keith D. Allen	R-325	5578
	7590	12/02/2003	EXAMINER	
Deltagen, Inc. 740 Bay Road Redwood City, CA 94063			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/005,211	Applicant(s) ALLEN, KEITH D.	
	Examiner Celine X Qian	Art Unit 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-13 and 20-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 and 20-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-29 is/are allowed.
- 6) ☒ Claim(s) 30-34 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 10-13, 20-34 are pending in the application. Claims 10-13, 20-24 are withdrawn from consideration for being directed to non-elected subject matter. Claims 25-34 are currently under examination.

This Office Action is in response to the Amendment filed on 9/8/03.

#### ***Response to Amendment***

The rejection of claims 1-9 and 14-19 under 35 U.S.C. 112 1<sup>st</sup> paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1, 2, 8, 14 and 15 under 35 U.S.C. 112 2<sup>nd</sup> paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1-9 under 35 U.S.C. 103 (a) is moot in light of Applicant's cancellation of the claims.

Claims 30 and 31 are rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph for reasons discussed below.

Claims 32-34 are rejected under 35 U.S.C. 103 (a) for reasons set forth of the record mailed on 6/3/03 and further discussed below.

Claim 31 is objected to for reasons discussed below.

#### ***New Grounds of Rejection Necessitated by Applicant's Amendment***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: selection of ES cells that undergo homologous recombination.

The recitation of “wherein the pseudopregnant mouse gives birth” renders the claims indefinite because a pseudopregnant mouse cannot give birth. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansour et al. (1988, Nature, vol. 336, No. 24, 348-352), in view of Guo et al. (AF).

Claims 32-34 are rejected under 35 U.S.C. 103 (a) for same reason as applied to claims 1-9 set forth in the previous office action. The recitation of “wherein the target construct, when introduced into...exhibits anti-depressive behavior when compared to a wild type mouse” is intended use for the claimed targeting construct. Such recitation does not carry patentable weight. Therefore, the rejection still applies to these claims.

Mansour et al. teach a strategy for targeted disruption of the *hprt* gene and proto-oncogene *int-2* in mouse embryonic stem cells and subsequent generation of knockout mice. Their teaching addresses the previous technical difficulty of obtaining embryonic stem cell carrying non-selectable, targeted gene mutation at loci of interest, and therefore provides a model which can be used to produce homozygous mutation of any gene, regardless of its function, if a cloned fragment of the gene is available (see page 348, second paragraph, line 1-3, third paragraph, line 1-5, and page 352, fourth paragraph, line 1-3). Mansour et al. further teach the generation of two targeting constructs, pRV9.1/TK and pINT-2-N/TK, each contains two sequences from an *hprt* gene and an *int-2* gene respectively, and a neo selection marker gene in between the two sequences (see page 350, figure 3). However, Mansour et al. do not teach how to make a PKDL2 target construct and knockout mouse.

Guo et al. teach that mutations in PKD1, PKD2, PKDL and REJ are four known member of polycystins that share significant homology with each other (see page 241, 1<sup>st</sup> col. lines 1-4). Guo et al. teach the cloning and characterization of a novel polycystin family member PKDL2 in mouse and human. Guo et al. further provide the nucleic acid sequence encoding Guo et al. teach the cloning and characterization of a novel polycystin family member PKDL2 (see page 243, Figure 1). Guo et al. teach that knockout mouse models of PKD1 and PKD2 illustrate their critical role in the development of kidney and pancreas. Guo et al. also teach that PKDL2 belong to PKD2 subgroup and share structural homology with cation channels such as voltage gated Ca<sup>+</sup>, Na<sup>+</sup> and K<sup>+</sup> channel families. Guo et al. further teach that PKDL2 might be implicated in 5q syndrome.

It would have been obvious to one of ordinary skill in the art at the time of filing to make a PKDL2 knockout construct to generate a cell deficient of PKDL2 protein or a PKDL2 transgenic knockout mouse because of the combined teachings of Mansour et al. and Guo, which provide a general method of making targeted disruption of specific gene in mouse genome to study its function and the importance in studying the PKDL2 function. The ordinary artisan would have been motivated to do so to study the precise role PKDL2 plays in facilitate membrane permeability or whether it has any implication in 5q syndrome. The level of skill in the art of making gene targeting constructs and subsequently generating knockout mouse is high, absent evidence to the contrary, one of ordinary skill in the art would have reasonable expectation of success to make a PKDL2 knockout construct as claimed. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Claim Objections***

Claim 31 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Conclusion***

Claims 25-29 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 10-13 and 20-24 drawn to an invention nonelected with traverse in the amendment filed on 5/5/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

*Anne-Marie Falk*

**ANNE-MARIE FALK, PH.D.**  
**PRIMARY EXAMINER**